Insmed Initiates Clinical Study for Follow-on Biologic Version of Neulasta(R)

RICHMOND, Va., Oct 14, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Company's INS-20 Receives Regulatory Clearance to Begin Phase I Clinical Trial

Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, today announced that it has received approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to initiate a Phase I clinical study for the Company's second follow-on biologic (FOB) product candidate, INS-20. Insmed's INS-20 is a pegylated recombinant form of human G-CSF, and an FOB of the FDA-approved product Neulasta(R), which had U.S. sales of approximately $2.4 billion in 2007.

Pre-clinical studies demonstrated that INS-20 and FDA-approved Neulasta(R) are comparable in both their pharmacological and toxicological profile. Detailed analytical characterisation also demonstrated that the products have a high degree of similarity. Data from these initial evaluations have been used, in part, to support the Phase I study, which will be initiated immediately. The Phase I study will be conducted in the United Kingdom and will compare the safety and establish the bioequivalence of INS-20 to Neulasta(R). Results from the trial are anticipated in 2009, and are expected to be used as part of a submission to the FDA to establish a protocol with the agency for a Phase III trial.

"We continue to be pleased by the progress we are making in the development of our FOB portfolio, utilizing our unique protein drug development capabilities and technical expertise," said Dr. Geoffrey Allan, President and CEO of Insmed. "Each development milestone we achieve is further evidence of our strong position as a leader in this evolving industry. We intend to use the data to be generated from the Phase I trial, in combination with the positive pre-clinical results previously garnered, as the basis for discussions with the FDA in an effort to establish a Phase III development path for INS-20."

The initiation of this FOB trial is the second of two planned for 2008 as part of Insmed's development of a portfolio of FOBs. In July 2008, the Company announced that a completed Phase I clinical trial had demonstrated the bioequivalence of INS-19, the Company's recombinant human granulocyte colony stimulating factor (G-CSF), compared to Neupogen(R), an FDA-approved G-CSF product for the treatment of neutropenia that recorded 2007 sales of approximately $1 billion. Insmed intends to seek approval of INS-19 and INS-20 in the U.S. and launch the products on expiration of the relevant innovator patents, which is in 2013 for Neupogen(R) and 2015 for Neulasta(R).

The Follow-on Biologics Market

According to published reports, an estimated $10 billion worth of biologic drugs are expected to come off patent by 2010, with an additional $10 billion by 2015. FOBs would provide safe and effective therapies at a reduced cost following the expiration of the original product's patent. A recent econometric study by economist Dr. Robert J. Shapiro, former Under Secretary of Commerce in the Clinton Administration, found that "...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans $67 billion to $108 billion over 10 years and $236 billion to $378 billion over 20 years."

About INS-20

Pegylated recombinant human G-CSF is a chemically modified version of G-CSF in which a water soluble polymer called polyethylene glycol is attached to the protein. The pegylated protein has a prolonged biological activity after it is injected into the patient. This allows less frequent dosing for the patient compared to recombinant human G-CSF. The FDA approved version of this drug is Neulasta(R). INS-20 is Insmed's follow-on biologic version of Neulasta(R).

About Insmed

Insmed Inc. is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. For more information, please visit www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our entrance into the follow on biologics market may be unsuccessful, we may be unable to secure an appropriate business partner for our follow-on biologics business, our common stock could be delisted from the Nasdaq Capital Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2007. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.